

Diagnostic accuracy of rapid diagnostic tests for the early detection of leptospirosis

ABSTRACT

Background: Leptospirosis is often misdiagnosed with several other tropical febrile illnesses in Malaysia due to similarities in clinical manifestations. Although treatment regimens could be started based on clinical judgments, early diagnosis has become paramount as a guide to chemotherapeutic interventions. Confirmed laboratory diagnosis through MAT or PCR is time consuming and usually available only in reference laboratories and not practical in healthcare settings. Rapid and easy to perform diagnostic tests are widely used in these settings as the point of care diagnosis. The present study was undertaken to compare the diagnostic performance of two IgM based immunodiagnostic assay kits for acute leptospirosis. **Methods:** A total of 50 serum samples were collected from patients clinically suspected for acute leptospirosis on admission in the Hospital Serdang, from June 2016 to June 2017. All the samples were subjected to MAT, lipL32 PCR and the two rapid tests (Leptocheck-WB and ImmuneMed Leptospira IgM Duo Rapid test). **Results:** Out of the 50 clinically suspected patients sampled, 19 were confirmed positive for leptospirosis. Six (12%) were confirmed by MAT and 13 (26%) by PCR. Similarly, of the 50 clinically suspected cases, 17 (34%) showed positivity for Leptocheck-WB and 7 (14%) for ImmuneMed Leptospira IgM Duo Rapid test. The overall sensitivity and specificity was 47.37% and 80.65% for Leptocheck-WB, and 21.05% and 90.32% for ImmuneMed Leptospira IgM Duo Rapid test. In another set of previously confirmed MAT positive samples (1:400-1:3600) obtained from a reference laboratory, Leptocheck-WB showed higher sensitivity (90.72%) than ImmuneMed Leptospira IgM Duo Rapid test (40.21%), and comparable specificity for ImmuneMed Leptospira IgM Duo Rapid test (88.89%) and Leptocheck-WB (82.86%). **Conclusion:** The sensitivity was higher for Leptocheck-WB and had a comparable specificity with ImmuneMed Leptospira IgM Duo Rapid test. Therefore, based on the present study, Leptocheck-WB is found to be a more sensitive rapid immunodiagnostic test for acute leptospirosis screening in hospital settings.

Keyword: ImmuneMed Leptospira IgM Duo Rapid test kit; Leptocheck-WB rapid diagnostic kit; Leptospirosis; Malaysia; Rapid diagnostic test

